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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR      | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/723,852      | 11/28/2000  | Christopher Brian Brodeur | 760-19              | 6459             |

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EXAMINER

THALER, MICHAEL H

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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3731

DATE MAILED: 09/02/2003

15

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application N .

09/723,852

Applicant(s)

BRODEUR ET AL.

Examiner

Michael Thaler

Art Unit

3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 13 August 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-5,9-13 and 15-18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5,9-13 and 15-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

Art Unit: 3731

Claims 1-5, 9-13 and 15-18 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. It is unclear what the term "non-continuous", as used in this application, means and therefore what structure it represents. Page 7, lines 21-22 of the specification states "Non-continuous, as used herein, refers to a tubular structure which is not substantially uninterrupted along its length". It is unclear if "along its length" means that 1) the structure is interrupted as one follows the longitudinal axis of the tubular structure or 2) the structure is interrupted either as one follows the longitudinal axis of the tubular structure or as one follows the circumference of the tubular structure and this interruption occurs along the length of the tubular structure (as shown at 4 in figure 1, for example). Further, it is unclear what the term "perimetrically non-continuous", as used in this application, means and therefore what structure it represents. It is unclear if this term means 1) that the structure is non-continuous as one follows the circumference of the tubular structure (as shown at 4 in figure 1, for example) or 2) that the structure is non-continuous as one follows either the circumference

Art Unit: 3731

or the longitudinal axis of the tubular structure. An example of a structure which is non-continuous as one follows the longitudinal axis of the tubular structure is a series of members (indicated by reference numeral 7 in figure 2) wherein each member is a 360 degree ring spaced longitudinally from the other rings. In this case the "perimeter" is simply the entire surface of the tubular structure. Also, it appears that second body 7 (figure 2) and second body 10 (figure 3) extend only partially in the circumferential direction since they are termed "strips" in the specification. Yet, the second bodies (e.g. second bodies 7 and 10) are referred to as a tubular bodies throughout the specification. Thus, it is unclear from the disclosure if second bodies 7 and 10 are tubular bodies which extend completely 360 degrees circumferentially or not. In other words, it is unclear if each of the three rectangular blocks on the right side of figure 2 represents a tubular body which extends completely 360 degrees circumferentially or not. If it does, it is not seen how it can be considered a strip. If it does not, it is unclear where the other strips are which form a tube with the rectangular strip shown.

Claims 1-5, 9-13 and 15-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant

Art Unit: 3731

regards as the invention. The meaning of the terms "non-continuous" and "perimetrically non-continuous" is unclear for the reasons set forth above. Further, it is unclear if "lengthwise" in claim 17, line 7, for example, means 1) parallel to the longitudinal axis of the tubular body or 2) at least having a component which extends along the length of the tubular body (e.g. a helix).

Claims 1-5, 9-13, 15 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ray (EP 0893108). Ray shows first substantially continuous PTFE tubular body 4, second perimetrically non-continuous tubular body (the longitudinally extending strips of the coupling member described in col. 9, lines 13-21) formed of polytetrafluorethylene (as indicated in col. 16, lines 20-31) and support structure 6. The Ray specification fails to specifically state that axial and radial compliance is provided to the prosthesis. However, it would have been obvious that axial and radial compliance is provided to the prosthesis due to the gaps between the strips. As to claim 3, note col. 7, lines 24-26 which indicates that the coupling member may be located on the inner rather than the outer surface of the stent. As to claim 6, note col. 10, lines 42-46.

Art Unit: 3731

Claims 16 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Layne et al. (6,398,803). Layne et al. show first perimetrically non-continuous polytetrafluorethylene inner tubular body (one set of circumferentially arranged strips extending between openings 44 of the inner "lacey" graft described in col. 5, lines 29-42 and which extend longitudinally only a distance equal to the width of each opening as measured in the longitudinal direction of the tubular member), second perimetrically non-continuous outer tubular body (one set of circumferentially arranged strips extending between openings 44 of the outer "lacey" graft described in col. 5, lines 29-42), support structure 30, both the outer and inner tubular body being formed of strips 48. Since only a portion of the Layne et al. inner and outer "lacey" grafts are considered to meet the claimed terms "tubular inner body" and outer tubular body", these portions are each "non-continuous along the entire length of said tubular bodies" as claimed. In other words, the "lacey" graft shown in figure 2 may be considered as comprising a series of longitudinally extending interconnected bodies. The first body at the end of the graft is continuous around its circumference. The second body consists of a plurality of strips between the openings 44. The third body is continuous around its circumference and so on, with

Art Unit: 3731

the bodies alternating between being circumferentially continuous and non-continuous. One of these circumferentially non-continuous bodies is considered to be the claimed body. The Layne et al. specification fails to specifically state that axial and radial compliance is provided to the prosthesis. However, it would have been obvious that axial and radial compliance is provided to the prosthesis due to the openings between the strips.

Applicant's arguments filed Dec. 26, 2002 and March 17, 2003 have been fully considered but they are not persuasive. The bottom of page 3 of the remarks filed March 17, 2003 refer to the "clarifying comments regarding these terms" on page 3 of the Response dated December 19, 2002. In those comments it is stated "By way of explanation, the specification on page 7, lines 19-22 defines the term **non-continuous** as a tubular body which is substantially uninterrupted along its length". However, this makes no sense since a tubular body which is substantially uninterrupted along its length is continuous rather than non-continuous. The last sentence on page 4 of the remarks filed March 17, 2003 is still not understood. If bodies 7 and 10 are continuous around the entire circumference of the tubular body, then is not seen how it can be considered a "strips". If they are "perimetrically non-continuous", does that mean that each of the 3 segments at 7 in

Art Unit: 3731

figure 2 and each of the 6 segments at 10 in figure 3 may have a structure similar to that shown at 4 in figure 1? If so, where does the original disclosure disclose this? As to the remarks filed August 13, 2003, the original disclosure is still unclear as to the meaning of the terms discussed above. Further, the reference to figure 5 on page 4 of the remarks is not understood since no figure 5 exists in this application. The statement on page 4 that 7 shows strips arranged longitudinally adjacent to form a tubular structure is not understood. Does this mean that each strip is actually a complete short tube? If so where does the original disclosure disclose this? As to the rejections based upon prior art, the reference to "Longitudinally extending strips" in col. 9, lines 18-21 of Ray clearly refers to strips that extend along (parallel to) the longitudinal axis of the prosthesis since such strips are "Longitudinally extending". Further, the use of this phrase rather than the term "helical" (which is used to describe other embodiments) indicates that a structure other than helical is intended. It would have been obvious that these strips are non-overlapping since the strips shown in the figures are non-overlapping. Although only a portion of the Layne body 42 is used to meet the terms of the claims, the claims do not preclude this.



Art Unit: 3731

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Thaler whose telephone number is (703) 308-2981. The examiner can normally be reached Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J. Milano can be reached on (703)308-2496. The fax phone numbers for the organization where this application or proceeding is assigned are

Application/Control Number: 09/723,852

Page 9

Art Unit: 3731

(703)305-3590 for regular communications and (703)305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0858.

mht  
August 27, 2003



MICHAEL THALER  
PRIMARY EXAMINER  
ART UNIT 3731